

k120903

JUL 13 2012

5. 510(k) Summary

Device Trade Name: Acumed Congruent Bone Plate System: Acu-Loc 2 Plate

Manufacturer: Acumed, LLC
5885 NW Cornelius Pass Road
Hillsboro, OR 97124

Contact: Ms. Brittany Cunningham
Regulatory Specialist
Phone: 503.207.1467
Fax: 503.686.7102

Prepared by: Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
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Date Prepared: March 23, 2012

Classifications: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories
21 CFR 888.3040, Smooth or threaded metallic bone fixation fastener

Class: II

Product Codes: HRS; HWC

Indications For Use:

The Acumed Congruent Bone Plate System provides fixation for fractures, fusions, or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.

Device Description:

The Acu-Loc 2 Plate is a volar plate which is intended to provide fixation for distal radius fractures.

The purpose of this Special 510(k) is to add 2.3mm Locking Variable Angle Screws for use with the Acu-Loc 2 Plate. All components are made of titanium alloy conforming to ASTM F136.

This addition does not affect the intended use of the device or alter the fundamental scientific technology of the device.

Predicate Device:

The subject 2.3mm Variable Angle Locking Screws are substantially equivalent to predicate screws and pegs (K102998) with respect to indications, design, function, and materials.

Preclinical Testing:

The new screws were subjected to mechanical testing to characterize the screw/plate interface. The results demonstrate that the acceptance criteria defined in the Design Control Activities Summary were met.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Acumed, LLC
% Ms. Brittany Cunningham
Regulatory Specialist
5885 Northwest Cornelius Pass Road
Hillsboro, Oregon 97124-9432

JUL 13 2012

Re: K120903

Trade/Device Name: Acumed Congruent Bone Plate System: 2.3 mm Variable Angle
Locking Screw for Use with Acu-Loc2 Plate

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and
accessories

Regulatory Class: Class II

Product Code: HRS, HWC

Dated: June 14, 2012

Received: June 15, 2012

Dear Ms. Cunningham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

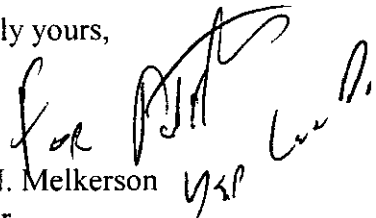
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "for M.N. Melkerson".

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K120903

Device Name: Acumed Congruent Bone Plate System

The Acumed Congruent Bone Plate System provides fixation for fractures, fusions, or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.


Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120903